





PTO/SB/08B (08-03)

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<b>Substitute for form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	10/673,629
		Filing Date	September 29, 2003
		First Named Inventor	Hector F. DeLuca
		Art Unit	1616
		Examiner Name	
Sheet 2	of 3	Attorney Docket Number 1256-00923	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
SH		The Merck Manual, Sixteenth Edition, 1992, pg. 1357.	
		Boris et al, "Relative Activities of Some Metabolites and Analogs of Cholecalciferol in Stimulation of Tibia Ash Weight in Chicks Otherwise Deprived of Vitamin D," Vitamin D Metabolites, Analogs and Bone Ash, 1976, pp. 194-198.	
		Hedlund et al, "Increased Incidence of Hip Fracture in Osteoporotic Women Treated with Sodium Fluoride," Journal of Bone and Mineral Research, Vol. 4, No. 2, 1989, pp. 223-225.	
		Hollick et al, Harrison's Principle of Internal Medicine, 13th Ed. 1994, pp. 2137-2151.	
		Jensen et al, "Treatment of Post Menopausal Osteoporosis, A Controlled Therapeutic Trial Comparing Oestrogen/Gestagen, 1,25-Dihydroxy-Vitamin D-3 and Calcium," Clinical Endocrinology, 16, 1982, pp. 515-524	
		Meunier, "Evidence-Based Medicine and Osteoporosis: A Comparison of Fracture Risk Reduction Data from Osteoporosis Randomised Clinical Trials," IJCP, Vol. 53, No. 2, March, 1999.	
		Nordin et al, "The Metabolic Basis of Osteoporosis," Osteoporosis: Physiological Basis, Assessment, and Treatment, Elsevier Science Publishing Co., Inc., 1990, pp.23-36.	
		Ott et al, "Calcitriol Treatment is not Effective in Postmenopausal Osteoporosis," Annals of Internal Medicine, Vol. 110, No. 4, February 15, 1989, pp. 267-274.	
		Peck, "The Pathogenesis of Postmenopausal Osteoporosis," Osteoporosis: Physiological Basis, Assessment, and Treatment, Elsevier Science Publishing Co., Inc., 1990, pp. 3-6.	
SH		Riggs et al, "Bone Turnover Matters: The Raloxifene Treatment Paradox of Dramatic Decreases In Vertebral Fractures without Commensurate Increases in Bone Density," Journal of Bone and Mineral Research, Vol. 17, No. 1, 2002, pp. 11-13.	

Examiner Signature		Date Considered	5/31/04
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Sheet 3 of 3	Attorney Docket Number	1256-00923	

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SH		Riggs et al, "Causes of Age-Related Bone Loss and Fractures," Osteoporosis: Physiological Basis, Assessment, and Treatment, 1990, pp. 7-16.	
		Christensen, Abstract PMID: 6795047, "Effect of 1,25-Dihydroxy-Vitamin D3 in Itself or Combined with Hormone Treatment in Prevent Postmenopausal Osteoporosis," Eur. J. Clin. Invest., August 11, 1981, Vol. 11, No. 4.	
		Klein, "Nutritional Rickets and Osteomalacia," Primer on the Metabolic Bone Diseases and Disorders of Mineral Metabolism, 1996, pp. 301-305.	
		Kleerekoper, "Treatment of Osteoporosis with Sodium Fluoride Alternating with Calcium and Vitamin D," Osteoporosis: Recent Advances in Pathogenesis and Treatment, 1981, pp. 441-448.	
		Sarkar, "Relationships Between Bone Mineral Density and Incident Vertebral Fracture Risk with Raloxifene Therapy," Journal of Bone and Mineral Research, Vol. 17, No. 1, 2002, pp. 1-10.	
		Cummings et al, "Improvement in Spine Bone Density and Reduction in Risk of Vertebral Fractures During Treatment with Antiresorptive Drugs," The American Journal of Medicine, Vol. 112, 2002, pp. 281-289.	
		Sudhaker Rao et al, "Metabolic Bone Disease in Gastrointestinal Hepatobiliary, and Pancreatic Disorders," Primer on the Metabolic Bone Diseases and Disorders of Mineral Metabolism, 1996, pp. 306-311.	
		Watts et al, "Intermittent Cyclical Etidronate Treatment of Postmenopausal Osteoporosis," The New England Journal of Medicine, Vol. 323, No. 2, July 12, 1990, pp. 73-79.	
SH		Harris, "Four-Year Study of Intermittent Cyclic Etidronate Treatment of Postmenopausal Osteoporosis: Three Years of Blinded Therapy Followed by One Year of Open Therapy," The American Journal of Medicine, Vol. 95, December 1993, pp. 557-567.	

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